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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,833	07/21/2003	Richard A. Schumacher	MEMORY-0028	4785

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ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,833	SCHUMACHER ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) *8-20,23-35,38-50,53-65,68-80,83-95 and 98-110* is/are withdrawn from consideration.

5)☒ Claim(s) *113* is/are allowed.

6)☒ Claim(s) *1-7, 51, 52, 66, 67, 96, 97, 111 and 112* is/are rejected.

7)☒ Claim(s) *1-7,21,22,36,37,51,52,66,67,81,82,96,97,111 and 112* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/04, 3/04, 9/2/05*, 9/16/06
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *121205*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Substance of Interview including description of the general nature of what was discussed: Applicants' representative confirmed that the election of Group 1 filed 22 September 2005 is for claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-113 and not for claims 1-41, 57--61 and 66 as stated on page 2 of the remarks section, which were mistakenly cited for Group I..

DETAILED ACTION

Claims 1-113 are currently pending in the instant application. Claims 8-20, 23-35, 38-50, 53-65, 68-80, 83-95 and 98-110 are withdrawn from consideration as being for non-elected subject matter. Claims 1-7, 51, 52, 66, 67, 96, 97, 111 and 112 are rejected and claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-112 are objected to as containing non-elected subject matter.

Election/Restrictions

Applicants' election of Group I, claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-113, and the further election of the compound N-(3-ethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-N-aminbenzoic acid with traverse in the response filed 22 September 2005 is acknowledged.

Applicants' traversal is on the grounds that the examiner should proceed in accordance with MPEP 809.02(c). Applicants' argue that 35 USC 121 does not permit restriction within a single claim and that the claims are Markush claims and should be examined according to MPEP 803, citing In re Weber, In re Haas, In re Harnish and Ex parte Hozumi.

In response to applicants' traversal, it is noted that the restriction requirement was made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict

the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. No where do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Rather, applicant has argued that these claims are Markush claims. However, there has been no rejection made under improper Markush groups so In re Harnish and Ex parte Hozumi, cited by applicants, are not relevant here. So, here we have claims, which involve more than one independent or distinct inventions. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. Applicant further argues In re Haas and In re Weber. However, this is considered non-persuasive because these two decisions involved rejections of claims under 35 USC 121 and not a restriction as is the case herein. The issue here is one of restriction. 35 USC 121 gives the Commissioner the authority to restrict to one invention those applications which contain two or more inventions, I.e. limit the examination of an application to a single invention. Thus, the requirement to restrict in this application is predicated on the fact that the elected subject matter taken as a whole and the non-elected subject matter taken as a whole are so different in structure and element as to be patentably distinct, I.e. a reference which anticipated but one group of compounds would not even render obvious the other group. Applicants further traverse the restriction requirement base on its intra-claim restriction. Again, it is noted that the restriction requirement here is predicated on the premise that the various compounds involved (I.e. the elected and non-elected compounds) differ in structure and element so much so as to be patentably distinct. So,

here we hae claims, which involve more than one independent or distinct invention. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. Accordingly, restriction as has been presented in this application is proper.

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination** is:

The products of formula I wherein:

R1 is H and alkyl as defined in claim 2;

R2 is Alkyl as defined in claim 1,

Cycloalkyl as defined in claim 1,

Cycloalkylalkyl as defined in claim 1,

Aryl as defined in claim 1,

Arylalkyl as defined in claim 1, and

A partially unsaturated carboxylic group having 5 to 14 carbon atoms as defined in claim 1;

R3 is Heteroarylalkyl group, wherein the heteroaryl is pyridyl, the alkyl portion, which is branched or unbranched, has 1 to 5 carbon atoms, the heteroarylalkyl group is unsubstituted or substituted one or more times in the heteroaryl portion by halogen, alkyl, alkoxy, cyano, trifluoromethyl, CF3O, nitro, oxo, amino, alkyl amino, dialkylamino, or combinations thereof and/or substituted in the alkyl protion by halogen, cyano, or methyl or combinations thereof;

R4 is Cycloalkyl as defined in claim 1 and aryl as defined in claim 1;

R5 is H,

Alkyl as defined in claim 1,

Alkylamino or dialkyl amino as defined in claim 1,

A partially unsaturated carbocycle-alkyl group as defined in claim 1,

Cycloalkyl as defined in claim 1,

Cycloalkylalkyl as defined in claim 1,

Aryl as defined in claim 1 and

Arylalkyl as defined in claim 1;

L is as defined as in claim 1;

R6 is as defined in claim 1 and the products of claim 113.

The remaining subject matter of claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-112 not drawn to the above elected invention and the subject matter of claims 8-20, 23-35, 38-50, 53-65, 68-80, 83-95 and 98-110 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of formula I wherein R2 is a heterocyclic group, or a heterocyclic-alkyl group; R3 is H, alkyl, a partially unsaturated carbocycle-alkyl group, an aryl alkyl group; R4 is a heteroaryl group; or R5 is a heterocyclic group or a heterocyclic-alkyl group.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for no elected subject matter differ materially in structure and

composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as, for example, by a thiazolidine, quinoline, thiophene, morpholine, oxazole, pyramiding, pyrazine, pyran, furan, etc., which are chemically recognized to differ in structure, function, and reactivity. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 549 subclass (200)+ furanyl, class 549 subclass (1)+ thiophene, class 548 subclass (215)+ oxazole and class 548 subclass (146)+ thiazole, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-112 are objected to as containing non-elected subject matter. Claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97 and 111-112 presented drawn solely to the elected invention for search and examination as identified supra would overcome the instant objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitations of L, R5 and R6 and their definitions in the compound according to formula I. However, there is insufficient antecedent basis for this limitation in the claim as the compound according to formula I in claim 2 has R4 as only a cycloalkyl and not an aryl or heteroaryl optionally substituted with R5-L. Therefore, claim 2 lacks antecedent basis as there is no L, R5 or R6 in the compound of the formula I. This rejection can be overcome by deleting the variables L, R6 and R6 and their definitions from the claim.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3-5 recite the limitation of "wherein at least one of R4 and R4 is other than H; and pharmaceutically acceptable salts thereof with the proviso that R4 is at least monosubstituted by R5-L..." However, there is insufficient antecedent basis for this limitation in claims 3 and 5 as there is no possible definition of R4 as H. There is insufficient antecedent basis for this limitation in claim 4 as some of the values of R4 as defined in claim 4 cannot be substituted by R5-L, for example, H and cycloalkyl and the claim has not limited R4 to only aryl or heteroaryl which can be substituted by R5-L. The rejection of claims 3 and 5 can be overcome by deleting "wherein at least one of R3 and R4 is other than H". The rejection of claim 4 can be overcome by amending the proviso to read "with the proviso that R4 is aryl or heteroaryl

as defined and at least monosubstituted by R5-L..." and deleting the proviso of "wherein at least one of R3 and R4 is other than H". The rejection of claim 5 can be overcome by

Commonly Assigned

Claims 1, 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 are directed to an invention not patentably distinct from claims 1, 2, 4-27, 40, 41, 45 and 66 of commonly assigned US Patent No. 6,699,890. Specifically, US Patent No. 6,699,890 discloses the compounds, for example, of the formula N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid, which anticipates applicants' instant claims 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 and US Patent No. 6,699,890 discloses the compounds of claim 45 which are intermediates for the preparation which the compounds of the formula (I) which renders obvious applicants claim 1.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent No. 6,699,890, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004. The assignment data present in the instant application was executed at a time later than the time the invention in this application was made.

Claims 3, 51, 52, 4, 66, 67, 6, 96 and 97 are directed to an invention not patentably distinct from claims 1-7, 9-19, 31-55, 60, 66, 68 and 69 of commonly assigned US Patent Application Publication 2004/0152902 (US Patent Application 10/715819). Specifically, US Patent Application 10/715819 claims the compounds, for example, of the formula (I) such as, N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(1-oxy-3-pyridylmethyl)-3-aminobenzoic acid (conflicting claim 66) and conflicting claims 68 and 69 which disclose pharmaceutical compositions with 0.1 to 50 mg of the compound which anticipates applicants' instant claims 3, 51, 52, 4, 66, 67, 6, 96 and 97 wherein R1 is alkyl, R2 is cycloalkyl, R3 is pyridylmethyl substituted with oxo, R4 is aryl substituted by carboxy and R5-L wherein L is a single bond and R5 is H.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent Application 10/715819, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this

application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004. The assignment data present in the instant application was executed at a time later than the time the invention in this application was made.

Claims 1, 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 are directed to an invention not patentably distinct from claims 1-11, 20-40, 52, 53 and 57 of commonly assigned US Patent application 10/754,600. Specifically, US Patent Application NO. 10/754,600 discloses the compounds, for example, of the formula N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid, which anticipates applicants' instant claims 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 and US Patent Application NO. 10/754,600 discloses the compounds of claim 57 which are intermediates for the preparation which the compounds of the formula (I) which renders obvious applicants claim 1.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent Application 10/754,600, discussed above,

would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004. The assignment data present in the instant application was executed at a time later than the time the invention in this application was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 4-27, 40, 41, 45 and 66 of U.S. Patent No. 6,699,890. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Patent No. 6,699,890 claims compounds of the formula (I) (conflicting claims 1, 2 and 4-27), such as N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid; N-(3-cyclopentyloxy-4-difluoromethoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid (conflicting claim 25), compounds X through compound cc (claim 26) and compound n, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl-4-

aminobenzoic acid (claim 27). Conflicting claims 40 and 41 disclose pharmaceutical compositions of the compound of the formula (I) and 0.1 to 50 mg of said compound in the composition which anticipates applicants instantly claimed invention of claims 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 and therefore is considered obviousness-type double patenting. Conflicting claim 45 claims intermediate compounds of the formula wherein R1 can be H which as seen on column 9 of the specification are compounds of the formula I wherein R2, R3 and R4 are as previously defined for formula I and R1 can be H. Reacting a compound wherein R1 is H is seen on column 9. Conflicting claim 45 in addition to conflicting claim 27 renders applicants' instant claim 1 as obvious, and therefore rejected under obviousness type double patenting as conflicting claim 45 claims intermediates wherein R1 can be H as found in claim 1 and claim 27 discloses a compound of the formula (I) which differs from applicants' instant claim 1 by only position R1. The motivation would be to prepare additional intermediate compounds to prepare compounds of the formula (I), such as compound n of claim 27.

Claims 3, 51, 52, 4, 66, 67, 6, 96 and 97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-19, 31-55, 60, 66, 68 and 69 of copending Application No. 10/715819. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Patent Application No. 10/715819 claims the compounds, for example, of the formula (I) such as, N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(1-oxy-3-pyridylmethyl)-3-aminobenzoic acid (conflicting claim 66) and conflicting claims 68 and 69 which disclose pharmaceutical compositions with 0.1 to 50 mg of the compound

which anticipates applicants' instant claims 3, 51, 52, 4, 66, 67, 6, 96 and 97 wherein R1 is alkyl, R2 is cycloalkyl, R3 is pyridylmethyl substituted with oxo, R4 is aryl substituted by carboxy and R5-L wherein L is a single bond and R5 is H. Therefore, conflicting claims 1-7, 9-19, 31-55, 60, 66, 68 and 69 anticipates applicants' instantly claimed invention and therefore the claims are rejected under obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1, 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-11, 20-40, 52, 53 and 57 of U.S. Application No. 10754,600. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Patent Application NO. 10/754600 claims compounds of the formula (I) (conflicting claims 1-11) and formula (IV) conflicting claims 20-36, such as, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl-4-aminobenzoic acid (claim 37-40). Conflicting claims 52 and 53 disclose pharmaceutical compositions of the compound of the formula (I) and 0.1 to 50 mg of said compound in the composition which anticipates applicants instantly claimed invention of claims 3, 4, 6, 7, 51, 52, 66, 67, 96, 97, 111 and 112 and therefore is considered obviousness-type double patenting. Conflicting claim 57 claims intermediate compounds of the formula wherein R1 can be H, which as seen on column 6 of the Pre-grant publication of the specification, are compounds of the formula I wherein R2, R3 and R4 are as previously defined for formula I and R1 can be H.

Reacting a compound wherein R1 is H is seen on column 6. Conflicting claim 57 in addition to conflicting claims 37-40 renders applicants' instant claim 1 as obvious, and therefore rejected under obviousness type double patenting as conflicting claim 57 claims intermediates wherein R1 can be H as found in claim 1 and claims 37-40 discloses a compound of the formula (I) which differs from applicants' instant claim 1 by only position R1. The motivation would be to prepare additional intermediate compounds to prepare compounds of the formula (I), such as compound p of claim 40.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 21, 22, 51, 52, 66, 67, 96, 97, 111 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,699,890.

The applied reference has a common assignee and some common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent No. 6,699,890 discloses compounds of the formula (I), specifically, for example, the compounds of the formulas: N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid; N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid; N-(3-cyclopentyloxy-4-difluoromethoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid; N-(3-cyclopropylmethoxy-4r-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid; N-(3-cyclopropylmethoxy4-difluoromethoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid; and N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid (see claim 26, column 55. US Patent No. 6,699,890 also discloses the compounds in pharmaceutical compositions containing 0.1 to 50 mg of the compound (see claims 40 and 41). US Patent No. 6,699,890 discloses compounds and pharmaceutical compositions which anticipate applicants instant claims wherein R1 is alkyl, R2 is cycloalkyl, R3 is pyridylmethyl and R4 is phenyl substituted with COOH which corresponds to R4 as aryl substituted with carboxy and R5-L wherein L is a single bond and R5 is H.

Claims 1, 3, 4, 6, 7, 21, 22, 51, 52, 66, 67, 96, 97, 111 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2004/0230072.

The applied reference has a common assignee and some common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent Application Publication 2004/0230072 discloses compounds of the formula (I), specifically, for example, N-(3-cyclopropylmethoxy-4r-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid; (see claims 1-11 and 20-40, specifically compound p, claim 40). US Patent Application Publication 2004/0230072 also discloses the compounds in pharmaceutical compositions containing 0.1 to 50 mg of the compound (see claims 52 and 53). US Patent Application Publication 2004/0230072 discloses compounds and pharmaceutical compositions which anticipate applicants instant claims wherein R1 is alkyl, R2 is cycloalkyl, R3 is pyridylmethyl and R4 is phenyl substituted with COOH which corresponds to R4 as aryl substituted with carboxy and R5-L wherein L is a single bond and R5 is H.

Claims 1, 3, 4, 6, 7, 21, 22, 51, 52, 66, 67, 96, 97, 111 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0149052.

The applied reference has a common assignee and some common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent Application Publication 2003/0149052 discloses compounds of the formula (IV) [page 4, paragraph [0047], specifically, for example, N-(3-cyclopropylmethoxy-4r-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid; page 21, cmpd a, [0437]. US Patent Application Publication 2003/0149052 also discloses the compounds in pharmaceutical compositions containing 0.1 to 50 mg of the compound (page 14 [0243] and page 16 [0264]). US Patent Application Publication 2003/0149052 discloses compounds and pharmaceutical compositions which anticipate applicants instant claims wherein R1 is alkyl, R2 is cycloalkyl, R3 is pyridylmethyl and R4 is phenyl substituted with COOH which corresponds to R4 as aryl substituted with carboxy and R5-L wherein L is a single bond and R5 is H.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over US Patent No 6,699,890

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Determining the scope and contents of the prior art

US Patent No. 6,699,890 claims compounds of the formula (I) (conflicting claims 1, 2 and 4-27), such as N-(3-cyclopentyloxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid; N-(3-cyclopentyloxy-4-difluoromethoxyphenyl)-N-(3-pyridylmethyl)-3-aminobenzoic acid (conflicting claim 25), compounds X through compound cc (claim 26) and compound n, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl-4-aminobenzoic acid (claim 27). Conflicting claims 40 and 41 disclose pharmaceutical compositions of the compound of the formula (I) and 0.1 to 50 mg of said compound in the composition. Conflicting claim 45 claims intermediate compounds of the formula wherein R1 can be H which as seen on column 9 of the specification are compounds of the formula I wherein R2, R3 and R4 are as previously defined for formula I and R1 can be H. Reacting a compound wherein R1 is H is seen on column 9.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is the compounds of the formula I as found in the prior art reference do not allow R1 to be H, however, the prior art does prepare compounds which only differ by applicants' position R1, such as, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which only differs by R1 being alkyl. Furthermore, the prior art reference provides description of intermediate compounds which only differ by position R1, such as

wherein R1 is hydrogen, which are useful for the preparation of compounds of the formula I.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds of the formula I wherein R1 is H when faced with the prior art reference which discloses compounds of the formula I, which are useful for depression or pyschosis, specifically, the compound of N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which differs from applicants instantly claimed compound by the position equivalent to R1 as alkyl instead of hydrogen. However, It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., an anti-pyschosis). Furthermore, the prior art reference discloses intermediate compounds, which correspond to compounds of formula I, wherein R2, R3 and R4 are as found for formula I and wherein R1 can be H. Therefore, one would be motivated to prepare compounds of applicants' instantly claimed compound with the expectation of preparing intermediates for the preparation of compounds of the formula I, such as N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid which is useful for the treatment of pyschosis.

Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over US Patent Application Publication, 2004/0230072.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Determining the scope and contents of the prior art

US Patent Application Publication, 2004/0230072 claims compounds of the formula (I) (conflicting claims 1-11) and formula (IV) conflicting claims 20-36, such as, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl-4-aminobenzoic acid (claim 37-40). Conflicting claims 52 and 53 disclose pharmaceutical compositions of the compound of the formula (I) and 0.1 to 50 mg of said compound in the composition.

Conflicting claim 57 claims intermediate compounds of the formula wherein R1 can be H, which as seen on column 6 of the Pre-grant publication of the specification, are compounds of the formula I wherein R2, R3 and R4 are as previously defined for formula I and R1 can be H. Reacting a compound wherein R1 is H is seen on column 6.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is the compounds of the formula I as found in the prior art reference do not allow R1 to be H, however, the prior art does prepare compounds which only differ by applicants' position R1, such as, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which only differs by R1 being alkyl. Furthermore, the prior art reference provides description of intermediate compounds which only differ by position R1, such as wherein R1 is hydrogen, which are useful for the preparation of compounds of the formula I.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds of the formula I wherein R1 is H when faced with the prior art reference which discloses compounds of the formula I, which are useful for depression or pyschosis, specifically, the compound of N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which differs from applicants instantly claimed compound by the position equivalent to R1 as alkyl instead of hydrogen. However, It is well established

that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., an anti-pyschosis). Furthermore, the prior art reference discloses intermediate compounds, which correspond to compounds of formula I, wherein R2, R3 and R4 are as found for formula I and wherein R1 can be H. Therefore, one would be motivated to prepare compounds of applicants' instantly claimed compound with the expectation of preparing intermediates for the preparation of compounds of the formula I, such as N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid which is useful for the treatment of pyschosis.

Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over US Patent Application Publication 2003/0149052.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application

and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Determining the scope and contents of the prior art

US Patent Application Publication 2003/0149052 discloses compounds of the formula (IV) [page 4, paragraph [0047], specifically, for example, N-(3-cyclopropylmethoxy-4r-methoxyphenyl)-N-(3-pyridylmethyl)4-aminobenzoic acid; page 21, cmpd a, [0437]. US Patent Application Publication 2003/0149052 also discloses the compounds in pharmaceutical compositions containing 0.1 to 50 mg of the compound (page 14 [0243] and page 16 [0264]). Furthermore, page 6 [0088] discloses intermediate compounds of the formula wherein R1 can be H, which are compounds of the formula I wherein R2, R3 and R4 are as previously defined for formula I and R1 can be H. Reacting a compound wherein R1 is H is seen on column 6.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is the compounds of the formula I as found in the prior art reference do not allow R1 to be H, however, the prior art does prepare compounds which only differ by applicants' position R1, such as, N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which only differs by R1 being alkyl. Furthermore, the prior art reference provides description of intermediate compounds which only differ by position R1, such as

wherein R1 is hydrogen, which are useful for the preparation of compounds of the formula I.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds of the formula I wherein R1 is H when faced with the prior art reference which discloses compounds of the formula I, which are useful for depression or pyschosis, specifically, the compound of N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid, which differs from applicants instantly claimed compound by the position equivalent to R1 as alkyl instead of hydrogen. However, It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., an anti-pyschosis). Furthermore, the prior art reference discloses intermediate compounds, which correspond to compounds of formula I, wherein R2, R3 and R4 are as found for formula I and wherein R1 can be H. Therefore, one would be motivated to prepare compounds of applicants' instantly claimed compound with the expectation of preparing intermediates for the preparation of compounds of the formula I, such as N-(3-cyclopropylmethoxy-4-methoxyphenyl)-N-(3-pyridylmethyl)-4-aminobenzoic acid which is useful for the treatment of pyschosis.

Non-elected Subject Matter Claim Rejections - 35 USC § 102

The following 35 USC 102(b) rejections apply to non-elected subject matter.

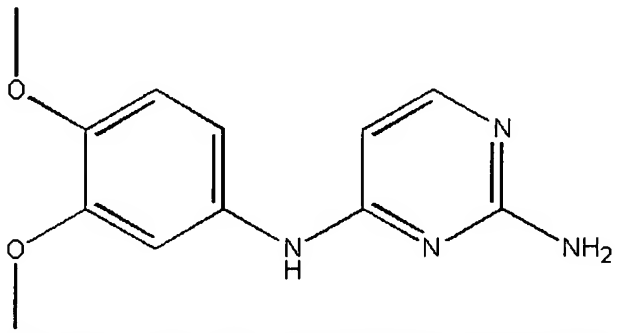
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The non-elected subject matter of claims 4, 66 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2 729 142.

FR 2 729 142 discloses the compounds of the formula (I) which are useful for the treatment of cardiac arrhythmia, page 1 and 2. Effective quantities of the compounds, such as 1 to 30mg and pharmaceutical compositions are found on page 12. The compound of D2 is disclosed on page 17 and corresponds to applicants' instant non-elected subject matter of claim 4 wherein R1 and R2 are alkyl, methyl, R3 is heteroarylalkyl, pyridylmethyl, and R4 is H which corresponds to applicants' proviso wherein one of R3 and R4 is other than H.

The non-elected subject matter of claims 3, 4 and 6 are rejected under 35 USC 102(b) as being anticipated by C. Kenneth Banks.

C. Kenneth Banks discloses the compound of formula 12, 2-amino-4-(3'-4'-dimethoxyanilino)-pyrimidine:



2-amino-4-(3'-4'-dimethoxyanilino)-pyrimidine

Which corresponds to the non-elected subject matter of claims 3, 4 and 6 wherein R1 and R2 are alkyl, R3 is H, and R4 is heteroaryl substituted by amino and R5-L wherein L is a single bond and R5 is H.

The non-elected subject matter of claims 1, 3, 4 and 6 are rejected under 35 USC 102(b) as being anticipated by US Patent No. 4,524,373 which discloses the compound of example 80, Table 6, columns 27 and 28, 4-(o-biphenyl)aminophenol derivatives wherein R5 is H, X is methoxy, Y is H, which corresponds to applicants' non-elected subject matter of claim 1 wherein R1 is H, R2 is alkyl, R3 is H and R4 is aryl substituted by R5-L wherein L is a single bond and R5 is aryl.

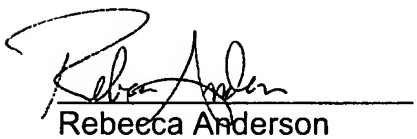
Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



December 12, 2005

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